



COURAGE Chronicle

Courage Chronicle February 2000

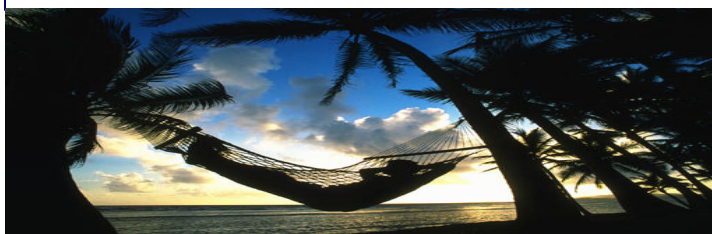
1st ANNUAL COURAGE TRIAL MEETING

We'd like to thank all of you who took time out of your busy schedules to attend the annual meeting in San Diego. The warm weather and venue were a great reprieve from the northern snows of January!

A significant highlight of the meeting was the enthusiasm displayed by the Coordinators and PIs who discussed their successes with patient enrollment and follow-up. COURAGE is truly about providing comprehensive medical care to all study patients and we ask that you utilize donated study drugs as much as possible. It was inspiring to hear about some of the "extra" steps performed by PIs and Coordinators who went above and beyond the call of duty for their patients. It's often that extra phone call to patients to explain their drug regime, diet, or what's expected of them at their next follow-up appointment that makes a critical difference between success and failure.

Another important issue that emerged at the meeting was the need to send your **completed** CRF forms and original ECGs to the West Haven Coordinating Center and Chairman's Office ASAP so that we can collect necessary trial data. We ask that you submit these forms within 2 weeks of randomization and all follow-up visits. Similarly, please send angiographic films, nuclear studies and lipid samples to the respective core labs ASAP. This will ensure that information is being recorded correctly and missing data or queries can be identified and resolved in a timely manner.

Finally, if you add a new Sub-PI, **it is essential to complete the 'Addendum to FDA Form 1572, "Statement of Investigator" Form** and send it to the Pharmacy Coordinating Center **along with updated CVs**. Also, for all new personnel, please fill out the "Change of Participating Investigator/Coordinator" form found in section 12 of the Operations Manual and fax it to Liz Petrokaitis at the West Haven Coordinating Center.



IMPORTANT NUMBERS TO REMEMBER

☎ **William Boden, MD** (315) 477-4529
Pager: 1-800-759-7243 pin # 5010640

☎ **Robert O'Rourke, MD** (210) 617-5100
1-888-338-4936
Pager: 1-888-605-8906

☎ **Karen Potter, BSN** (315) 476-7461 Ext. 2806
1-800-215-7330

☎ **Paul Casperson, PhD** (210) 617-5288
☎ **Pharmacy Coordinating Center** (505) 248-3203
Carol Fye, RPh, MS
Lorina Gifford, BS

RANDOMIZATION CALLS:

Toll Free: **(888) 803-5560** OR
For VA's – FTS (700) 428-extension

☎ **Ray Kilstrom** (203) 932-5711 ext. 3767
☎ **Joan Smith** (203) 932-5711 ext. 3765
☎ **Liz Petrokaitis** (203) 932-5711 ext. 3760
☎ **Tassos Kyriakides** (203) 932-5711 ext. 3771
☎ **Pamela Hartigan** (203) 932-5711 ext. 3773
☎ **Tenya Economou** (203) 932-5711 ext. 3762
☎ **Pager: 800 Number available by the end of February**

Important Reminder from West Haven Coordinating Center

➤ According to the Good Clinical Practice (GCP) guidelines, we are required to have written documentation that each patient enrolled in the study has given consent to participate in the study. Usually, this is a copy of the signed informed consent document. The IRB's at some sites, however, do not allow coordinators to send copies of the signed informed consent document off site. In these cases, it is sufficient for us if we receive a letter, signed by the PI, stating that the patient (study number xxx-x-xxx) has been informed about the study, understands the study, and has signed the consent document.

A prototype letter can be found in your COURAGE Operations Manual on page 8-11. Thank you in advance!!

PATIENT ENROLLMENT UPDATE

| | | |
|-----|--|----|
| 671 | Audie Murphy VAMC – San Antonio | 40 |
| 506 | Ann Arbor VA Medical Center | 23 |
| 202 | London Health Sciences Centre | 22 |
| 580 | Houston VA Medical Center | 20 |
| 558 | Durham VA Medical Center | 19 |
| 203 | Montreal Heart Institute | 18 |
| 205 | Queen Elizabeth II HSC | 14 |
| 308 | Mid America Heart Institute | 13 |
| 598 | John C. McClellan VA – Little Rock | 12 |
| 209 | Sunnybrook & Women's College HSC | 11 |
| 596 | Lexington VA Medical Center | 11 |
| 200 | Foothills Hospital | 10 |
| 306 | Mayo Clinic | 10 |
| 663 | Seattle VA Medical Center | 9 |
| 304 | Emory University Hospital | 8 |
| 501 | Albuquerque VA Medical Center | 8 |
| 210 | The Toronto Hospital | 7 |
| 626 | Nashville VA Medical Center | 7 |
| 630 | New York VA Medical Center | 7 |
| 313 | University of Oklahoma | 6 |
| 311 | SUNY Health Science Center at Syracuse | 5 |
| 312 | University of Michigan Medical Center | 5 |
| 207 | St. Paul's Hospital | 4 |
| 211 | University of Alberta Hospital | 4 |
| 302 | Cleveland Clinic | 4 |
| 508 | Atlanta VA Medical Center | 4 |
| 584 | Iowa City VA Medical Center | 4 |
| 201 | Hamilton General Hospital, McMaster Clinic | 4 |
| 301 | Boston Medical Center | 2 |
| 208 | Sudbury Memorial Hospital | 1 |
| 300 | Barnes-Jewish Hospital | 1 |
| 307 | Christiana Care Health Systems | 1 |
| 626 | Vanderbilt University | 1 |
| 204 | St. Michael's Hospital | 1 |

Total Patients as of 2/18/00: 316

IMPORTANT REMINDERS FROM THE ANGIOGRAPHIC CORE LAB!!!

- Please send your CDs or cines of baseline angiograms and PCI procedures to the angiographic core lab within 2 weeks of randomizing your patient. Videograms are not acceptable and will be returned.
- Please notify the core lab if you need a film returned promptly and the film will be expedited back to you within 3 to 5 working days.
- ALL patients randomized into COURAGE MUST have an ejection fraction measured objectively within 30 days of randomization (not from the baseline angiogram). This is stated clearly in the protocol. It is not acceptable to just visualize the EF and estimate it. If an EF was not measured accurately on the angiogram due to PVC's or any other reason, you MUST obtain an EF by an alternate method within 30 days of the randomization date as long as no other intercurrent event has occurred since the angiogram was done at baseline. The angiographic core lab will notify you if you need to get an alternate method of EF performed on your patient.



ECG Core Lab News

When you are administering an ECG, make 2 copies: one to be placed in your source documentation and one to be sent to the West Haven Coordinating Center. Photocopying the ECGs can distort the complexes and make it difficult to analyze them.

When baseline wandering occurs on the ECG, check your electrodes for proper attachment. To prevent baseline wandering, practice proper skin preparation which entails cleaning the areas of electrode placement with an alcohol swab and drying the area with a cotton ball. If excess artifact occurs, check if the ECG machine is sharing the outlet with another device [or just run the ECG on battery power], make sure the patient is not clenching their fists and check your lead wires to see if they are frayed. For the most part, artifacts can be traced to the limb leads. Thus, you can use this rule of thumb:

| Noise/Artifact in | = | Check Electrode |
|-------------------|---|-----------------|
| I, II, aVR | = | RA |
| II, III, aVF | = | LL |
| I, III, aVL | = | LA |
| All leads | = | RL |
| V1 | = | V1 |

Noise/artifact in 3 associate leads are usually caused by muscular tension such as clenched fist or tight shoulders.

Just remind the patients to **relax**, and check your electrode connections.



Just a reminder, you should properly label all ECGs and send them to Ray who will forward them to the CEL.



CRF's Available Soon!!

The newly revised NCR version of the CRF's will be distributed to your site approximately by mid-April. Once they are available, you will no longer be required to make copies. Please send the original completed forms within two weeks of enrollment to the West Haven Coordinating Center, one copy to the chairman's office and save one copy at your site.



Pharmacy Corner

IMPORTANT! Please fax your Drug Inventory reports to Lorina Gifford every two weeks: (505) 248-3205

For all SAE reports or study drug questions contact Carol Fye or Lorina Gifford.